Bifurcated coronary stents for infrapopliteal angioplasty in critical limb ischemia

Roberto Silingardi, MD,[a] Sebastiano Tasselli, MD,[b] Valentina Cataldi, MD,[a] Roberto Moratto, MD,[a] Stefano Gennai, MD,[a] Giovanni Coppi, MD,[c] Luigi Marcheselli, BA,[d] and **Gioacchino Coppi, MD,[a]**
Baggiovara, Trento, and Milan, Italy

Objective: **The goal of this article is to report the preliminary results of infrapopliteal percutaneous transluminal angioplasty stenting with the Nile Croco coronary bifurcated stent (Minvasys, Gennevilliers, France) for selected patients with critical limb ischemia (CLI).**
Methods: **From October 2006 to December 2010, 31 patients with CLI with below-the-knee TransAtlantic Inter-Society Consensus C and D lesions at the popliteal (n = 17, 54.8%) and distal tibioperoneal trunk (n = 14, 45.2%) bifurcations, with suboptimal primary percutaneous transluminal angioplasty results (residual stenosis >30%, elastic recoiling, or dissection), with at least two-vessel runoff to the foot (present or after percutaneous transluminal angioplasty), free of aortoiliac arterial disease, and at high surgical risk (more than three risk factors) were treated with the Nile Croco coronary bifurcated stent. Study end points included technical success, immediate and midterm primary and secondary patency rates, clinical improvement, and limb salvage.**
Results: **Technical success was achieved in all patients (100%) without any intraoperative complications. Early complications included an acute stent occlusion and an acute compartment syndrome for a collateral arterial branch perforation. Median follow-up was 12.1 months (range, 1-32). Primary and secondary patency rates were 96.7% and 86.2% (95% confidence interval [CI], 67.2%-94.6%) at 30 days and and 100% and 96.6% (95% CI, 78.0%-99.5%) at 1 year, respectively. Clinical improvement (an upward shift of at least two Rutherford categories) was achieved in 28 patients (90.3%). A major amputation was required in one patient (3.2%). The overall limb salvage rate at 1 year was 96.7% (95% CI, 78.6%-99.5%).**
Conclusions: **Preliminary data suggest that the Nile Croco bifurcated stent for below-the-knee angioplasty in selected patients with CLI is associated with high rates of technical success, early and midterm patency, and clinical improvement. Limb salvage rates are acceptable for this technically highly challenging anatomy, yet further studies with larger patient populations are necessary to validate these results. (J Vasc Surg 2013;57:1006-13.)**

Infrapopliteal percutaneous transluminal angioplasty (PTA) for the treatment of critical limb ischemia (CLI) is now considered an effective treatment and an established alternative to traditional surgical techniques.[1-4] An attempt at angioplasty before primary amputation or surgical bypass in patients at high surgical risk is recommended.[4,5] However, PTA is associated with low procedural success and high restenosis rates, with 3-year patency rates around 25%.[6] New developments in equipment and techniques have led to continuous improvements in PTA technical and clinical success rates, but technical failure in terms of hemodynamic residual stenosis, postdilatation arterial dissections, elastic recoil, and early thrombosis of treated segments persists.[7] Therefore, stenting for below-the-knee (BTK) treatment is increasingly being used. Recent studies on straight in-line arterial flow BTK treatment quote high clinical success rates >96%[3] and 1-year patency rates around 75%—a marked improvement compared with the 68.6% for PTA alone reported in the same study.[8] A meta-analysis comprising 640 patients treated with PTA stenting reported an in-stent restenosis rate of 25.7% at 1 year.[9]

BTK atherosclerotic lesions at bifurcations, however, prove to be technically more challenging; increase the risk of plaque shift to the side branch, stent thrombosis, and recurrent stenosis involving the main vessels or, more commonly, the side branch of bifurcated lesions. Additionally, main vessel patency is often achieved at the expense of the side branch, where restenosis rates remain relatively high.[10]

Materials and techniques for percutaneous coronary interventions (PCIs) have been developed to meet similar anatomical challenges in small-diameter vessels.[11] The authors hypothesized that these dedicated materials could also be applied to the endovascular treatment of infrapopliteal bifurcated lesions.

Hence, this study was prospectively designed to assess the safety and effectiveness, in terms of immediate and midterm outcomes, of a coronary bifurcated stenting

From the Department of Vascular Surgery, Nuovo Ospedale Civile S. Agostino-Estense Baggiovara,[a] and Centro Oncologico Modenese,[d] University of Modena and Reggio Emilia, Baggiovara; the Division of Vascular Surgery, Ospedale S. Chiara, Trento[b]; and the Department of Vascular Surgery, IRCSS San Raffaele, Milan.[c]
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Reprint requests: Gioacchino Coppi, MD, University of Modena and Reggio Emilia, Department of Vascular Surgery, Nuovo Ospedale S. Agostino Estense, Modena, Via Giardini, 1355, 41100 Baggiovara (MO), Italy (e-mail: chirvascmo@gmail.com; gioachino.coppi@unimore.it).
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device (Nile Croco intracoronary stent system; Minvasys, Genevilliers, France) for infrapopliteal angioplasty at tibial bifurcations in selected patients with CLI.

METHODS

Ethical approval for this study was not required at this institution.

Treatment protocol and patient selection. From January 2006 to December 2010, 816 patients with CLI were admitted to the Department of Vascular Surgery, Nuovo Ospedale Civile S. Agostino-Estense Baggiovara, and assessed for peripheral endovascular procedures. CLI was considered to be categories 4-6 according to the Rutherford classification,[12] evidenced as rest pain, nonhealing ulceration or gangrene that could require major amputation, plus evidence of diffuse pedal ischemia, resting ankle pressure <60 mm Hg, and toe pressure <30 mm Hg.[13,14]

All patients were preoperatively assessed with duplex ultrasound (DUS) scanning and submitted to angiography. All vascular lesions were classified according to the modified TransAtlantic Inter-Society Consensus (TASC) classifications for tibioperoneal occlusive disease.[14] A total of 325 patients with TASC C (stenoses 1-4 cm, occlusions 1-2 cm, and extensive stenoses at the tibial trifurcation) and D (occlusions >2 cm and diffuse tibial vessel disease) tibial lesions, mainly associated with multilevel lower limb disease, were treated with BTK angioplasty; of these, 97 patients were affected by isolated tibial disease—52 with PTA alone and 45 with PTA/stenting (in the case of suboptimal primary angioplasty results consisting of residual stenosis >30%, elastic recoil, or flow-limiting dissection).

Patients with CLI with lesions at the infrapopliteal or tibioperoneal trunk bifurcations (n = 31) with at least two-patent-vessel runoff to the foot (present or after PTA distal to the related bifurcation), without aortoiliac arterial disease, and at high surgical risk (more than three risk factors) were selected for endovascular treatment with the Nile Croco bifurcated stent. Primary PTA was performed proximally or distally to the ostium of the bifurcation only and never in the bifurcation. In patients with inadequate runoff (less than two-patent-vessel runoff to the foot) after PTA revascularization, main vessel treatment only was performed, and according to previous stent indications, straight stents were used (n = 14).These patients were excluded from the current study.

In the same period, a total of 318 good-risk patients with CLI who had chronic long or total femoropopliteal occlusions or had failed attempted endovascular interventions were treated with bypass surgery; 125 included tibial bypass.

Data for all patients were prospectively collected in a computer database and retrospectively analyzed. Baseline demographic and clinical data are reported in Table I.

Procedure details. All patients were admitted to the vascular surgery department 1 day prior to the preprogrammed intervention, femoral access and run-in feasibility were assessed with DUS scanning, and ankle brachial index (ABI) and toe brachial index (TBI) measurements were taken. All endovascular interventions were performed in a dedicated angiographic room equipped with a C-Arm (OEC 9800; GE Medical System, Salt Lake City, Utah), intravascular ultrasound (IVUS, Eagle Eye Gold; Volcano Therapeutics, Rancho Cordova, Calif), and a DUS scanner (Esaote AU 5, Genova, Italy). In cases of multilevel disease in other lower limb locations, the extreme distal lesions were treated first. All procedures were performed under local anesthesia. Ipsilateral antegrade percutaneous access was used in 21 cases (67.7%) and retrograde contralateral percutaneous access in crossover in the remaining 10 patients (32.3%). Introducer sheaths (Cordis, Miami, Fla) ranged from 5F to 6F, with crossover procedures treated preferentially with a 6F reinforced introducer sheath (Accuflex Bipore, Northvale, NJ). A standardized endovenous bolus of 5000 IU of unfractionated heparin was administered systematically.

Prior to endovascular treatment, diagnostic angiography was performed to quantify lesion extent (Fig 1). All infrapopliteal stenoses and occlusions were crossed with a 0.014-inch (Asahi Grand Slam PTCA guidewire; Abbott Vascular, Abbott Park, Ill) or 0.035-inch guidewire (Terumo Medical, Somerset, NJ).

Materials and interventional bifurcated stenting technique. The Nile Croco bifurcated stent is a balloon-expandable chromium-cobalt bare metal stent with a short scaffold at the side port to provide coverage of the side-branch ostium and allow access to the side branch. The

Table I. Patient clinical and lesion characteristics

Number of patients	31
Male/female ratio	21/10
Age, years, mean (range)	71.6 (45-91)
Risk factors, number (%)	
Diabetes mellitus	25 (80.6%)
Hypertension	18 (58%)
Cardiac insufficiency (NYHA >I)	16 (51.6%)
Preexisting renal insufficiency (creatinine level >2 mg/dL)	11 (35.5%)
Chronic renal insufficiency (requiring dialysis)	4 (36.4%)
Dislipidemia (cholesterol >120 mg/dL)	9 (29%)
Current smoker	5 (16%)
Chronic obstructive lung disease	3 (9.7%)
High risk (>3 risk factors)	31 (100%)
Lesion classification	
Stage III (Fontaine)/category 4 (Rutherford)	2 (6.4%)
Stage IV (Fontaine)/category 5-6 (Rutherford)	29 (93.5 %)
Lesion location and classification, number (%)	
Popliteal bifurcation	17 (54.8%)
TASC C	11 (64.7%)
TASC D	6 (35.3%)
Tibioperoneal trunk	14 (43.2%)
TASC C	8 (57.1%)
TASC D	6 (42.9%)
Ankle brachial index, mean ± SD	0.42 ± 0.15
Toe brachial index, mean ± SD	0.42 ± 0.03

NYHA, New York Heart Association functional class; *SD,* standard deviation; *TASC,* TransAtlantic Inter-Society Consensus; *TASC C,* stenoses 1-4 cm, occlusions 1-2 cm, and extensive stenoses at the tibial trifurcation; *TASC D,* occlusions >2 cm and diffuse tibial vessel disease.

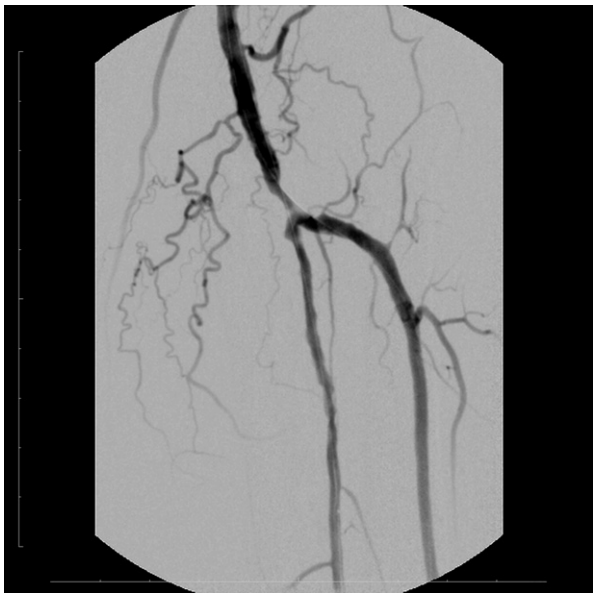

Fig 1. Preoperative angiographic image of an obtsructive lesion at the tibial bifurcation and inferior popliteal artery.

device is premounted on a dedicated delivery system (Fig 2). It is a single-operator device with independent catheter manipulation and pressure monitoring. The system allows for a strategy of main-branch stenting with optional side-branch stenting.

The system has two independent balloons (ranging in diameter from 2.5 to 3.5 mm for the main branch and from 2.0 to 3.0 mm for the side branch), which each have a rapid exchange lumen for the required two guidewires. The system requires a 6F guiding catheter (inner diameter ≥0.70 inch). The stent is divided into three cell design segments to create the same metal/artery ratio along the bifurcation and avoid cell overstretching. The system allows final kissing-balloon inflation in both the main and side branches.

The standard deployment procedure involves initial wiring (0.014-inch guidewire) of both the main- and side-branch vessels and advancement of the stent device over the lesion (Fig 3, *A*). The main-branch balloon is inflated and the bifurcated stent is deployed (Fig 3, *B*). The side-branch balloon can then be inflated (Fig 3, *C* and *D*). The delivery system is then removed (Fig 3, *E*). Additional treatment of the side branch, with additional balloon inflation or stent implantation, can be performed directly (Fig 4). The indications for stent implantation in the side branch were the presence of lesions not completely covered by the bifurcated stent side port.

Postoperative angiography confirmed technical success (Fig 5).

Postinterventional patient management. Postinterventional anticoagulation therapy included a dual-antiplatelet-aggregation regimen comprising 75 mg of clopidogrel and 100 mg of acetylsalicylic acid per day for 4 weeks, followed by at least one of these drugs indefinitely. Antithrombotic prophylaxis (low-molecular-weight heparin) was administered during the period of bed confinement (usually around 3 weeks) for concomitant wound therapy, according to the American College of Chest Physician Guidelines.[15] This center follows a wound care therapy algorithm already outlined by Alexandrescu et al.[16,17]

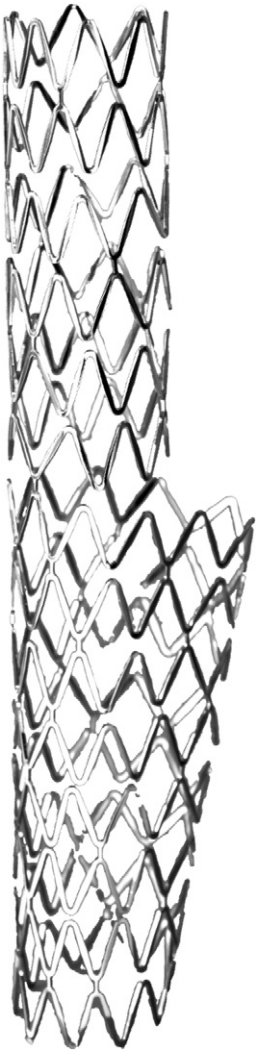

Fig 2. The Nile Croco chromium-cobalt bare-metal bifurcated stent with a short scaffold side port.

Outcome assessment and follow-up. Technical success was determined as less than 30% of final residual stenosis measured at the narrowest point of the treated segment. Patency was defined as the absence of recurrent occlusion causing more than 50% reduction in diameter of the treated segment, as documented by DUS scanning or angiography. A 50% stenosis was identified by DUS scanning when a peak systolic velocity of ≥200 cm/s developed and a 3:1 velocity ratio was seen across the lesion.

Ankle brachial index was evaluated both before and after revascularization procedures; in patients in whom

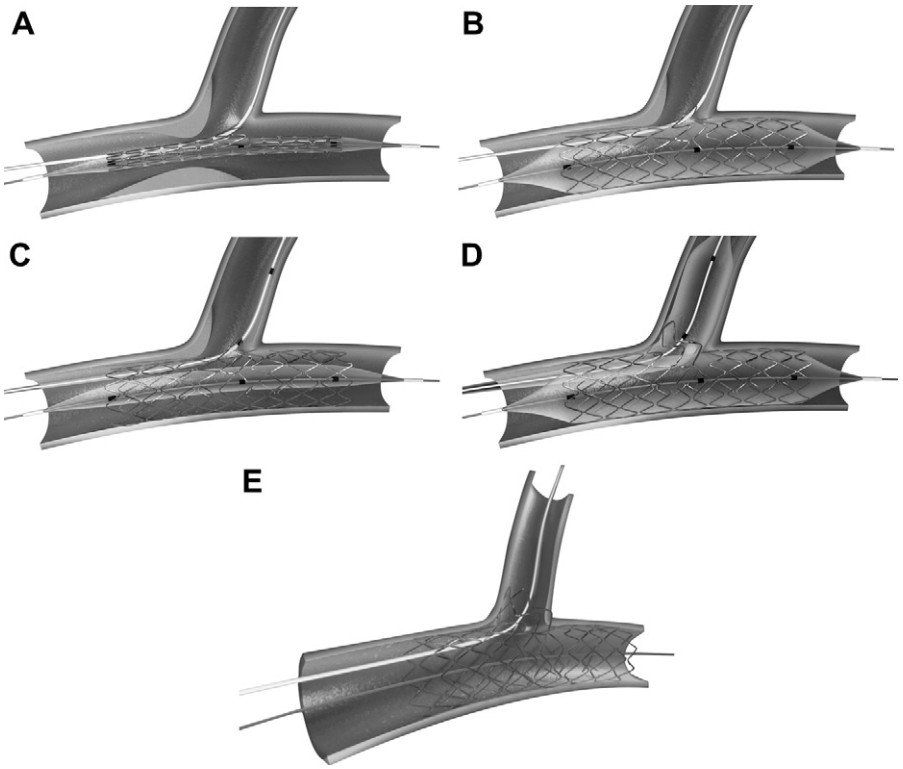

Fig 3. A, Advancement of the stent device over the lesion. **B,** Main branch balloon inflation for stent deployment. **C,** Advancement of the side branch balloon. **D,** Side-branch balloon inflation. **E,** Delivery system removal.

the ABI could not be accurately measured, toe pressure was recorded. Clinical improvement was achieved if there was a ≥0.10 increase in ABI and wound healing produced improvement of at least two Rutherford categories.[12] Primary and secondary patency rates, limb salvage, and amputation-free survival were defined according to recommended standards.[18]

Follow-up consisted of a clinical examination and DUS scanning at 1, 3, 6 and 12 months and biannually thereafter. Angiographic examinations were performed in selected patients with no observed clinical improvement and/or suspected restenosis or occlusion.

Study end points. Preliminary end points of this study were technical success, 30-day and 1-year primary and secondary patency rates, clinical improvement, and limb salvage. Secondary end points were intra- and postoperative complications and overall and amputation-free survival.

Statistical analysis. Quantitative data are expressed as mean values and standard deviations, and categorical data, as frequencies. Amputation-free survival was measured from the date of surgery to the date of last follow-up or the date of major amputation. Overall survival was defined from the date of surgery to the date of last observation or death resulting from any cause. Survival curves were calculated using Kaplan-Meier estimates, and 95% confidence intervals (CIs) with Greenwood's formula. The incidence rate was defined as the ratio of observed events to overall person-years of follow-up, or person-years of follow-up in specified intervals of time. Continuous variables were compared with the *t*-test.

RESULTS

Technical success was achieved in all cases (100%) as documented at final angiography. The Croco Nile bifurcated stent was deployed in all cases, and side-branch extensions were added in 19 cases (61.3%; Fig 4). No intraoperative complications were recorded. Operative data are outlined in Table II.

Study outcomes are provided in Table III. Immediate complications included one repeat PTA and percutaneous thromboaspiration at postoperative day 1 because of an acute occlusion of the stent at the popliteal bifurcation. A reintervention was also required for acute compartment syndrome associated with a collateral branch perforation of the posterior tibial artery. The patient was returned to the operating room and treated with a covered stent, fasciotomy, and surgical drainage of the hematoma. Another patient required proximal stenting and distal PTA to improve runin and runoff. Other complications included access site hematoma (n = 2) and persistence of chronic renal insufficiency (n = 1).

The mean follow-up was 12.1 months (range, 1-32). Recurrent in-stent restenosis was evidenced in three

Fig 4. Postoperative angiographic image of the bifurcated stent and the side-branch extension deployed.

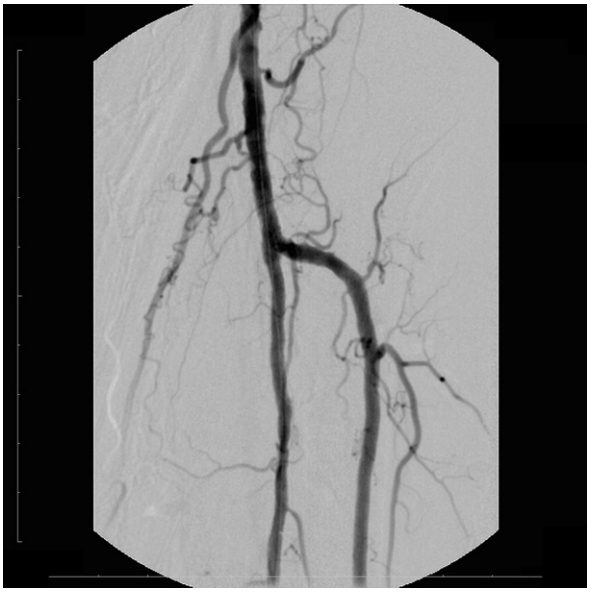

Fig 5. Final angiogram confirming technical success.

patients (9.7%) at 3, 18, and 23 months from the initial procedure, and was successfully treated with intrastent repeat PTA; one drug-eluting balloon (Dior; Eurocor Gmbh, Bonn, Germany) and two cutting balloons (Angiosculpt; Angioscore, Fremont, Calif) were employed.

Secondary procedures were necessary in three cases (9.7%) for distal stenosis in the peroneal artery also treated with PTA; in one patient, proximal PTA on the superficial femoral and popliteal arteries was necessary to improve inflow at 2 months, and in the other two patients with

Table II. Operative details

General operative details	
Access	
Ipsilateral (percutaneous + Proglide[a])	25 (81)
Contralateral	6 (19)
Additional bifurcation extension segments	19
Preplanned additonal procedures in other locations[b]	44
Iliac	1
Superficial femoral artery[c]	9
Popliteal[d]	7
Below the knee	27
Concurrent procedures	
AngioSculpt[e]	2
Intravenous ultrasound imaging	2
Filter	1

[a]Proglide, Abbott Vascular, Abbott Park, Ill.
[b]Percutaneous transluminal angioplasty with or without stenting.
[c]Of which one double adsorbable stent in the superficial femoral artery was deployed and one debulking with the Rotarex system (Straub Medical AG, Stardubstrasse, Switzerland) + percutaneous transluminal angioplasty because of popliteal intrastent restenosis and multiple stenosis at the level of the superficial femoral artery.
[d]One covered stent for popliteal aneurysm.
[e]AngioSculpt, AngioScore, Fremont, Calif.

Table III. Major and minor amputations during the follow-up period to 12 months

Variable	*30 days*	*3 months*	*6 months*	*12 months*
Patients, No.	31	29	23	16
Amputation, No. (%)				
Minor	3 (9.7)	2 (6.7)	3 (12)	3 (16)
Major	—	1 (3.3)	—	—

diffuse atherosclerotic disease of the tibial vessels, additional distal PTA and stenting procedures were performed to increase runoff at 3 and 4 months from the initial procedure (Table III).

Primary patency rates (Fig 6) were 96.7% and 86.2% at 30 days and 12 months, respectively (95% CI, 67.2%-94.6%; standard error [SE], 6.4%; 10.5 [95% CI, 3.9-28.0] × 100 person-years). Secondary patency (Fig 7) was 100% and 96.6% at 30 days and 12 months, respectively (95% CI, 78.0%-99.5%; SE, 3.4%; 8.5 [95% CI, 2.7-26.2] × 100 person-years).

Considerable clinical improvement of the entire patient cohort was noted as reflected by a significant increase in the ABI (preintervention, 0.42 ± 0.15; postintervention, 0.73 ± 0.12) and TBI (preintervention, 0.42 ± 0.03; postintervention, 0.79 ± 0.09) measured 12 to 24 hours after stent deployment ($P < .001$).

An improvement of at least two Rutherford categories was achieved in 28 patients (90.3%). Preplanned minor amputations were required in 13 patients (41.9%). A major amputation was necessary in a single patient only (3.2%) at 2 months.

The overall limb salvage rate was 96.7% (95% CI, 78.6%-99.5%; SE, 3.3%; 2.4 [95% CI, 0.3-17.2] × 100

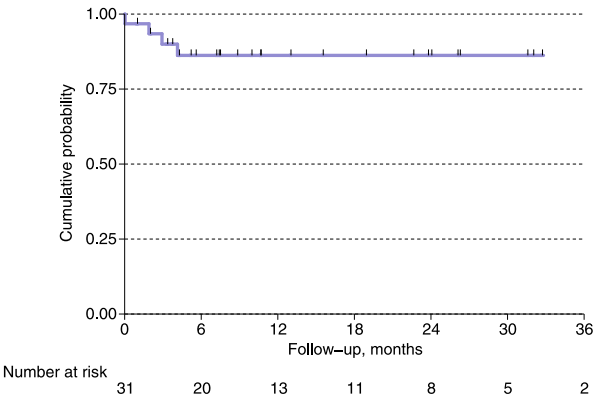

Fig 6. Overall primary patency for selected high-risk patients with critical limb ischemia (CLI) and lesions at the tibioperoneal bifurcations treated with the Nile Croco bifurcated stent.

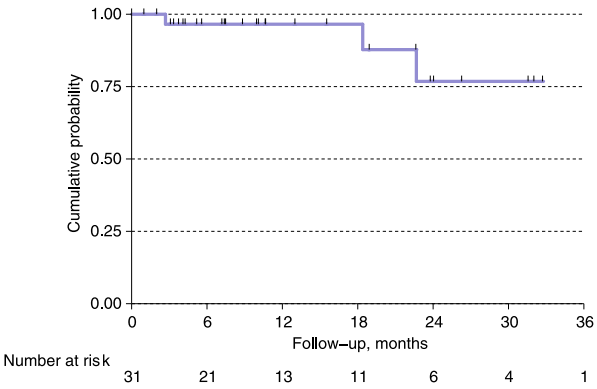

Fig 7. Overall secondary patency for selected high-risk patients with critical limb ischemia (CLI) and lesions at the tibioperoneal bifurcations treated with the Nile Croco bifurcated stent.

person-years) at 12 months (Fig 8). Major amputation-free survival at 12 months was 96% (95% CI, 77%-99%).

Six patients (19.4%) died during the follow-up period. The overall survival rate (Fig 9) at 12 months was 79.3% (95% CI, 59.5%-90.1%; SE, 7.9%; 16.1 [95% CI, 7.7-33.7] × 100 person-years).

DISCUSSION

Percutaneous transluminal angioplasty in infrapopliteal lesions is associated with acceptable clinical benefit, technical success, and rates of patency, limb salvage, and morbidity[19-21] but is plagued by complications throughout follow-up, such as high rates of recurrent stenosis, low primary patency rates, and amputations that question the subsequent durability of the procedure.[3,4]

Stent implantation, an already established treatment for iliac arterial occlusive disease,[22] was therefore employed in the tibial district. However, the small vessel diameter of tibial arteries and the prevalence of calcified and diffuse atherosclerotic disease have both been associated with low procedural success and higher restenosis rates[3,6,8,23] and, therefore, pose many challenges to PTA stenting.

With advances in endovascular therapy and technologies, together with the development of specifically designed materials for infrapopliteal arteries,[24-26] such as absorbable, carbofilm-coated, and coronary drug-eluting stents,[6,27,28] interest in primary and secondary stent-supported BTK angioplasty for CLI has increased. In a meta-analysis published in 2008 with 640 patients with predominantly straight in-line arterial flow treatment, the primary patency rate was 78.9%, the limb salvage rate was 96.4%, and Rutherford class improved in 91.3%.[9] The report concluded that the results are encouraging for selected patients, particularly those affected with diabetes.[9,29-35]

As studies dedicated to the BTK bifurcation are lacking in the literature, this study must be compared with results achieved in in-line arterial flow treatments, although the technical difficulty posed by the natural bifurcation is elevated because of increased risks of plaque shift to the side branch, stent thrombosis, and recurrent stenosis involving the main vessels or, more commonly, the side branch of bifurcated lesions. The incidences of these complications are difficult to estimate, because to our knowledge, dedicated data are unavailable in literature. Additionally, main vessel patency is often achieved at the expense of the side branch, where restenosis rates remain relatively high.[36] The incidence of BTK lesions at the bifurcation can only be estimated, as there are no data in the literature. However, coronary artery disease bifurcation lesions have been estimated to account for up to 15% of patients treated with percutaneous coronary intervention.[10]

A variety of double-stent strategies have been developed for the treatment of both the main vessel and the branch in bifurcation coronary lesions: simultaneous kissing Y, V, and T; crush; reverse-T; and culotte techniques (with varying degrees of overlap between the stents).[11] These techniques aim to achieve maximal apposition to the vessel wall but, as yet, have not yielded an improved clinical profile when compared with simple strategies, and randomized controlled trials have not yet been undertaken.[10,37]

These ongoing limitations underline the necessity for dedicated materials for BTK bifurcated lesions. Now three main types of stents dedicated to bifurcation treatment are commercially available[36]: preformed stents with side ports to facilitate access to the side branch after main vessel treatment, conical stents that follow the anatomical geometry of the ostium, and stents designed to treat the side branch first.

At this center, prior to 2006, patients with lesions at the tibial bifurcations were treated with PTA, surgical bypass, straight vessel stenting close to the bifurcation but not over the ostium, or, in nine cases, the kissing-balloon technique.[11,38-40] The results were unsatisfactory, and alternative techniques were considered. Hence, in 2006, while awaiting the development of dedicated BTK bifurcated lesion materials, technologies already available and in use for coronary artery bifurcation treatment were considered.

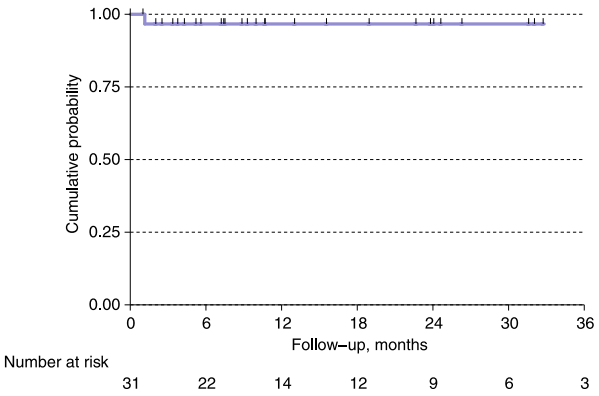

Fig 8. Overall limb salvage for 31 high-risk patients with tibioperoneal bifurcated lesions treated with the Nile Croco bifurcated stent.

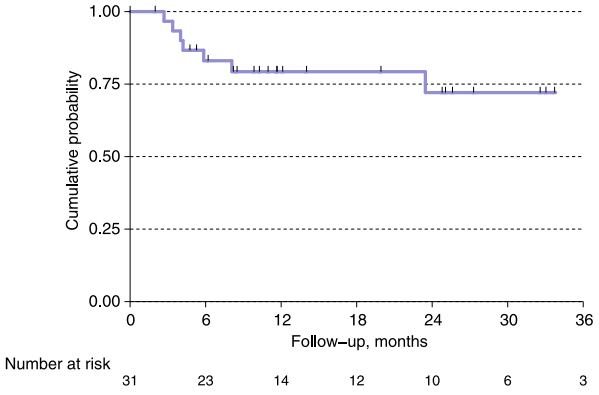

Fig 9. Overall survival for high-risk patients with tibioperoneal bifurcated lesions treated with the Nile Croco bifurcated stent.

The Nile Croco bifurcated stent, a conical stent, was selected in this series on the basis of the availability of poststenting kissing-balloon dilatation, optional side-branch stenting, the bifurcated stent structure (assumed by the authors to offer increased stability compared with straight in-line stenting or other two-stent techniques), and low balloon profiles (2-3.5 mm).

The treatment proposed in this study is appropriate for varying kinds of bifurcated lesions; the lesion is crossed by guidewires, with the possibility of choosing which tibial vessel should be restored throughout the main body and preserving direct access to the secondary vessel through the side branch.

Although technically demanding, technical success in this study was achieved in all (100%) patients. The two cases of complications were assumed to be linked to incomplete stent expansion in one case and device advancement in a complicated anatomy in the other. Despite issues linked to a learning curve, this study reports results at 1 year that are comparable to, if not more advantageous than, those reported in literature for in-line arterial flow BTK stenting: a 9.7% in-stent restenosis rate compared with an average of 25%[9] and an 86.2% primary patency rate compared with an average of 76%.[8,9] The high patency rates thereafter supported a high incidence of clinical improvement and a single major amputation at 12 months. Limb salvage in this study was also comparable, reporting a 96.7% vs a 96.4% recorded in the previously described meta-analysis.[9]

The major limitation of the present study is that it is a retrospective analysis of a prospectively designed, nonrandomized small patient cohort, without a comparative control group. Further, as limited outcome data are available in the literature regarding the treatment of BTK bifurcated lesions, comparisons with other treatment techniques are difficult to make. Therefore, comparisons have been made with straight in-line arterial flow BTK outcomes, even though the treatment outlined in this study is technically and anatomically more complicated.

CONCLUSIONS

These preliminary data represent high rates of technical success, early and midterm patency rates, and clinical improvement for selected patients with BTK bifurcated lesions treated with the Nile Croco bifurcated stent. Limb salvage rates are acceptable for this technically highly challenging anatomy, yet further studies with larger patient populations are necessary to validate the results.

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AUTHOR CONTRIBUTIONS

Conception and design: RS, ST, VC, RM, SG, GC, LM, GC
Analysis and interpretation: RS, ST, VC, SG, GC, GC
Data collection: RS, ST, VC
Writing the article: RS, ST, VC, GC
Critical revision of the article: RS, ST, VC, RM, SG, GC, LM, GC
Final approval of the article: RS, ST, VC, RM, SG, GC, LM, GC
Statistical analysis: ST, VC, LM
Obtained funding: Not applicable
Overall responsibility: RS, GC

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